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**ATTORNEY'S DOCKET NUMBER: 2002834-0115**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Caplan, et al. Examiner: Weddington, K.E.

Serial No.: 09/976,963 Art Unit: 1614

Filing Date: October 12, 2001

Title: CONDUCTANCE OF IMPROPERLY FOLDED PROTEINS  
THROUGH THE SECRETORY PATHWAY AND RELATED  
METHODS FOR TREATING DISEASE

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Certificate of Mailing	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
July 18, 2006	_____
Date	Signature
	Mary B. Wilson
Typed or Printed Name of person signing certificate	

Sir:

**TRANSMITTAL LETTER**


Enclosed **for filing** in the above-referenced patent application, please find the following documents:

1. Statement Filed Pursuant To The Duty Of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98 (Supplemental) (**6** pp.);
2. Supplemental Form PTO-1449 (**1** pp.);
3. Cited Art (**8** references);
4. Credit Card Payment form in the amount of \$180.00 (For IDS fee); and
5. Return-Receipt Postcard.

Please charge any additional fees associated with this filing, or apply any credits, to our Deposit Account No. 03-1721.

Respectfully Submitted,  
CHOATE, HALL & STEWART LLP

Date: July 18, 2006

  
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Sir:

**STATEMENT UNDER 35 CFR §§ 1.56, 1.97, & 1.98**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- [ ] An *original* Information Disclosure Statement; or  
[X] A *supplemental* Information Disclosure Statement.

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Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☐ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☐ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
  - ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☒ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☒ Certifies that *either*:

☒ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

☒ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

☒ Copies of references 1-8 are included;

☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

☒ Does not contain non-English language citations;

☐ Does contain non-English language citations, a concise

explanation of which is provided in the form of an abstract.

[ ] Includes one or more translations of a non-English citation.

#### Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

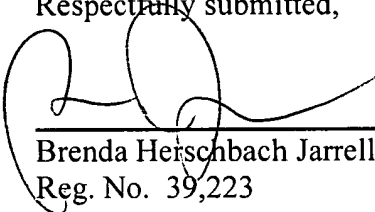
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and

3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated: July 18, 2006



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Brenda Herschbach Jarrell, Ph.D.  
Reg. No. 39,223

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U.S. Department of  
Commerce  
Patent and Trademark  
Office

Atty. Docket:  
2002834-0115

In re Application No.  
09/976,963

# **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

(Use several sheets if necessary)

Applicant: Caplan, et al.

Filing Date:  
October 12, 2001

Group:  
1614

## **U.S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass

## **U.S. PATENT APPLICATIONS**

Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:

## **FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
1.	WO96/32139	PCT	October 17, 1996		
2.	JP 09 028392	Japan	February 4, 1997	X	

## **OTHER DOCUMENTS**

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
3.	Neyses, et al., "Use of antisense oligonucleotides for selective inhibition of gene expression in adult cardiomyocytes", <i>Funktionsanalyse Biologischer Systeme</i> , 25:53-62 (1996) – ABSTRACT ONLY
4.	Seibert, et al., "Cystic fibrosis: Channel, catalytic, and folding properties of the CFTR protein", <i>Journal of Bioenergetics and Biomembranes</i> , 29:429-442 (1997) – ABSTRACT ONLY
5.	Moon, et al., "Calcium-stimulated- CL-secretion in Calu-3 human airway cells requires CFTR", <i>American Journal of Physiology</i> , 273:L1208-L1219 (1997).
6.	Robinson, et al., "Ca <sup>2+</sup> influx induced by the Ca <sup>2+</sup> -ATPase-inhibitors 2, 5-di-(t-butyl)-1, 4-benzohydroquinone and thapsigargin in bovine adrenal chromaffin cells", <i>Biochemical J.</i> , 288:457-463 (1992).
7.	Schmitz, et al., "In vivo iodination of a misfolded proinsulin reveals co-localized signals for Bip binding and for degradation in the ER", <i>EMBO Journal</i> , 14:1091-1098 (1995).
8.	Zhang, et al., "Quality Control in the Secretory Pathway: The Role of Calreticulin, Calnexin and BiP in the Retention of Glycoproteins with C-Terminal Truncations", <i>Molecular Biology of the Cell</i> , 8:1943-1954 (1997).
EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.